

Message Text

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73

ORIGIN HEW-06

INFO OCT-01 EA-10 ISO-00 OES-05 MED-03 /025 R

66618

DRAFTED BYDHEW/FDA/JRWEINROTH, MD.

APPROVED BY OES/SCI/BMP:MBEAUBIEN

DHEW/OIH/MACODDING

EA/ANP:HLANGE(INFO)

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R 102130Z MAR 75

FM SECSTATE WASHDC

TO AMEMBASSY WELLINGTON

UNCLAS STATE 053441

E.O. 11652: NA

TAGS: ETRD, EIND, OGEN, TBIO, NZ

SUBJ: FDA ADVISORY-DEFECTIVE RESPIRATOR-GILL I

1. FDA ADVISES THAT GILL RESPIRATOR MANUFACTURED BY GFM MEDICAL INC., WOBURN MASSACHUSETTS, AND DISTRIBUTED BY CHEMTRON CORP., MEDICAL PRODUCTS DIVISION, 1801 LILLY STREET, ST. LOUIS, MISSOURI PRODUCT NO. 621110 AND 621111-80 SERIAL NUMBERS 1011, 1014 1026, 1027, 1047, 1049, 1052, 1053, 1054, 1056, 1060, 1062, 1068, 1070, 1072, 1073, 1075, 1077, 1078, 1079, 1080, 1081, 1086, 1090, AND 1096 REQUIRE MODIFICATION FOR SAFE AND EFFECTIVE USE.

2. THE PROBLEM WITH THE DEVICE IS APPARENTLY DUE TO A FAILURE OF AN INTERNAL PRESSURE TRANSDUCER RESULTING IN THE FAILURE OF THE DEVICE TO CYCLE PROPERLY. ON JANUARY 24, 1975 CHEMETRON NOTIFIED CONSIGNEES OF A RETROFIT PROGRAM CONSISTING OF REPLACEMENT OF ONE PRINTED CIRCUIT BOARD, ADJUSTMENT OR REPLACEMENT AS NEEDED OF THE PRESSURE TRANSDUCER AND THE SUPPLY OF A THREE PAGE REVISION OF THE OPERATIONAL MANUAL. THE RETROFIT PROGRAM WAS TO BE COMPLETED FEBRUARY 1, 1975.

3. POST IS REQUESTED TO DETERMINE IF CONSIGNEE HAS RECEIVED INFORMATION BY TELEGRAM AND/OR LETTER REGARDING PROBLEM WITH UNCLASSIFIED

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GILL RESPIRATOR AND IF THEY HAVE RECEIVED THE RETROFIT PROGRAM

AND MATERIALS.

4. FOREIGN CONSIGNEE AS FOLLOWS: AUCKLAND HOSPITAL, PARK ROAD,
GLAFTON, AUCKLAND, NEW ZEALAND, SERIAL NUMBER 1057 SHIPPED
10-10-74.
INGERSOLL

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NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01 JAN 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: MEDICAL CARE, EQUIPMENT, RECALLS
Control Number: n/a
Copy: SINGLE
Draft Date: 10 MAR 1975
Decaption Date: 01 JAN 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Authority: n/a
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 JAN 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1975STATE053441
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Document Unique ID: 00
Drafter: FDA/JRWEINROTH, MD.
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Original Previous Classification: n/a
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Margaret P. Grafeld
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05 JUL 2006

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To: WELLINGTON
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